



## TECHNICAL DATA SHEET

0411-TDS-ENG-2024

CLORAL HIDRATO (EUR. PH.)		
DESCRIPTION DCI: CHLORAL HYDRATE		DESCRIPTION DOE: HIDRATO DE CLORAL
CAS Nº: 302-17-0	EC Nº: 206-117-5	AEMPS CODE: 1281A
MOL. WEIGHT: 165,42	MOL. FORMULA: C2H3Cl3O2	ARTICLE CODE: 0411

ATTRIBUTES	SHOULD BE
Appearance	Colourless, transparent crystals
Solubility	Very soluble in water, freely soluble in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Appearance of solution	Clear and colourless
pH	3.5 - 5.5
Chloral alcoholate	Complies
Chlorides	<= 100 ppm
Non-volatile residue	<= 0.1 %
Assay	98.5 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 11.0

### STORAGE

Keep the container tightly closed, in a cool, dry place. Protected from air and light.

### REMARKS

Chloral Hydrate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006 - ICH Q3C (R6) "Residual solvents".

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request. The above information does not exempt from the obligation to identify the product before use.